UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
WESTERN DIVISION

WILLIAM H. WISE, on behalf of himself and all others similarly situated, Plaintiff, v. **BAYER CORPORATION**, Defendant.	Court File No.: Civ. 01-5078

CLASS ACTION COMPLAINT
DEMAND FOR JURY TRIAL

Plaintiff, by and through undersigned counsel, respectfully represents that he has injuries common to all those similarly situated, has incurred damages arising out of the use of the drug Baycol, and therefore seeks, through class action proceedings, to represent and prosecute all claims for the nationwide class of all those similarly situated persons. In support of his complaint, Plaintiff alleges as follows:

JURISDICTION AND VENUE

1. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000.00 exclusive of interest and costs, and because this is an action by an individual and representative Plaintiff who is a citizen of a different state from the defendant.

2. Venue is proper in this District pursuant to 28 U.S.C. § 1391. Plaintiff is a resident of the Western District of South Dakota. Defendant advertised in this District, received substantial compensation and profits from sales of the drug in this District, and made material

omissions and misrepresentations and breached warranties in this District.

PARTIES

3. Plaintiff and proposed class representative, who appears individually and on behalf of all those similarly situated members of the proposed class, is a resident of Deadwood, South Dakota.

4. Defendant, Bayer Corporation, is an Indiana Corporation and a wholly owned subsidiary of Bayer AG. The corporate headquarters for Bayer Corporation is Pittsburgh, Pennsylvania. Bayer Corporation manufactures, markets and distributes Baycol throughout the world, including South Dakota.

5. The proposed class representative and named plaintiff seeks to represent the following class:

> "All persons throughout the United States who have used the drug Baycol, manufactured, distributed, sold and/or placed in the stream of interstate commerce by defendant, and: (a) who have sustained any injury or damage and thereby, or (b) who may suffer such injury or damage and thereby, or in the future as a result thereof, or (c) who require medical monitoring to promote the early detection of serious latent disease associated with this drug, or (d) who have sustained a justifiable fear of sustaining such injury or damage in the future as a result thereof."

FACTUAL ALLEGATIONS

6. In 1997 the drug Baycol was manufactured, tested, packaged and marketed by defendant in order to lower cholesterol in people. Since its introduction, it is believed that 700,000 Americans have used Baycol. It was forecast that the annual income would be 1 billion dollars. It is estimated that thousands of prescriptions have been written in South Dakota.

7. Defendant has encouraged and promoted the drug that is the subject of this suit.

8. At all times relevant, defendant, itself, or through others, did manufacture, create, design, test, label, package, supply, market, sell, advertise, and warn about, and/or distribute in interstate commerce, the product Baycol.

9. Baycol has been advertised by the defendant as an effective cholesterol drug.

10. Defendant was in control of the design, testing, manufacture, marketing and sales of Baycol.

11. Defendant made filing(s) with the FDA in conjunction with the approval process for Baycol in the United States.

12. Defendant's strategy, has been to market and sell these products aggressively by the false and deceptive omission of material information about the dangers and health risks associated with Baycol that they were required to provide to potential users and their prescribing care givers, and by failing to protect users from serious dangers which defendant knew, or should have known, would result from use of these products and by creating a misinformed or under informed community of prescribing care givers in an attempt to create a buffer from responsibility between defendant and those who would actually be using Baycol.

13. Defendant's marketing efforts, as a whole, falsely and deceptively sought to create the image and impression that the use of Baycol was safe for human use.

14. On information and belief, defendant downplayed and understand the health hazards and risks associated with the use of Baycol. Defendant falsely and deceptively kept relevant information from potential Baycol users and minimized prescriber concern regarding the safety of Baycol.

15. Defendant falsely and deceptively misrepresented or omitted a number of material facts regarding Baycol, including, but not limited to, the following:

a. The adverse health effects caused by Baycol including the frequency and severity of adverse events; and

b. The presence and adequacy of testing of Baycol.

16. By no later than 1997 defendant knew or should have known about the dangers associated with these drugs but took no action. At least as early as 1997 defendant was, or should have been aware of the information, which concluded that Baycol increased the risk of muscle cell damage.

17. Defendant failed to provide material information to the FDA concerning muscle cell damage in connection with the use of Baycol.

18. Notwithstanding the critical mass of evidence available to defendant concerning the health risks associated with the use of this drug, it was not until August 8, 2001 that defendant did withdraw the drug from the market.

19. Defendant knew or should have known that Baycol created significant risks of serious injuries or disorders, including muscle cell damage, as to which defendant failed to make proper, reasonable or adequate warnings.

20. Defendant failed to warn the public and physicians about the special risks for developing muscle cell damage associated with the use of Baycol.

21. The product warnings in effect during the time that Baycol was prescribed to the class was inadequate to alert prescribing physicians and consumer patients of the actual adverse health risks associated with these drugs which were then known (or should have been known) to the defendant.

22. Defendant failed to provide the FDA all information in its possession concerning the cases of all muscle cell damage associated with Baycol's use notwithstanding the fact that they were required to report all serious and unexpected side effects to the FDA.

23. As a result of his use of the drug Baycol, Plaintiff has sustained injuries and damages, and/or the aggravation of preexisting medical conditions. Plaintiff also suffers a justifiable fear that such conditions will worsen in the future.

24. As a result of his ingestion of the drug Baycol, Plaintiff has sustained these damages, which damages are typical of those sustained by those proposed class:

a. Past and future medical and health care expenses, including, without limitation, the cost of consultation with physicians about the potential risks of the drug Baycol and diagnostic studies;

b. Disability;

c. Past and future emotional distress, including, without limitation, justifiable fear of disease;

d. Loss of enjoyment of life;

e. Physical and mental pain and suffering;

f. Inconvenience;

g. Past and future mental anguish; and

h. Increased risk of contracting disease.

FIRST CAUSE OF ACTION
(Strict Liability - Failure to Warn)

25. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

26. The drug Baycol was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution, in that, and not by way of limitation, said product and its warnings, instructions and directions failed to warn of the dangerous propensities of said product, which risks were known or reasonably scientifically knowable to Defendant. The Defendant knew or should have known of the defective condition,

characteristics and risks associated with said product, as previously set forth herein.

27. At all times herein mentioned, the aforementioned product was defective, and Defendant knew that the product was to be used by the user without inspection for defects therein. Moreover, Plaintiff neither knew, nor had reason to know at the time of the use of the subject product, of the existence of the aforementioned defects.

28. As a result of the defective condition of the aforementioned product, Plaintiff suffered injuries and damages as alleged herein.

SECOND CAUSE OF ACTION
(Negligence)

29. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

30. At all times herein mentioned, Defendant had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe and adequately warn of the risks and dangers of the aforementioned product.

31. At all times herein mentioned, Defendant negligently and carelessly manufactured, designed, formulated, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold the aforementioned product and failed to adequately test and warn of the risks and dangers of the aforementioned product.

32. The defendant impliedly or expressly represented that the drug Baycol it manufactured, distributed and/or sold was safe for use and would not cause the adverse health effects described herein.

33. As a result of said negligence and carelessness of the Defendant, Plaintiff suffered injuries and damages as alleged herein.

THIRD CAUSE OF ACTION
(Negligence Per Se)

34. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

35. At all times herein mentioned, Defendant had an obligation not to violate the law, in the manufacture, design, formulation, compounding, testing, production, processing, assembly, inspection, research, distribution, marketing, labeling, packaging, preparation for use, sale and warning of the risks and dangers of the aforementioned product.

36. At all times herein mentioned, Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301, et seq., related amendments and codes and federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law, and other applicable laws, statutes and regulations.

37. Plaintiff, as a purchaser and consumer of the product, is within the class of persons the statutes and regulations described above are designed to protect, and Plaintiff's injuries are the type of harm these statutes are designed to prevent.

38. Defendant's acts constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331, and constitutes a breach of duty subjecting defendant to civil liability for all damages arising therefrom, under theories of negligence per se.

39. Defendant failed to meet the standard of care set by the following statutes and regulations, which were intended for the benefit of individuals such as Plaintiff, making Defendant negligent per se: (a) The labeling lacked adequate information on the use of the drug Baycol [21 C.F.R. Section 201.56(a) and (d)]; (b) The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitation: muscle cell

damage, kidney damage, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drug [21 C.F.R. 201.57(e)]; (c) There was inadequate information for patients for the safe and effective use of Defendant's drug [C.F.R. 201.57(f)(2)]; (d) There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Defendant's drugs [21 C.F.R. 201.57(f)(1)]; and (e) The labeling was misleading and promotional [21 C.F.R. 201.56(b)].

40. As a result of the violations of the statutes described above, Plaintiff suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION
(Breach of Implied Warranty)

41. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

42. Prior to the time that the aforementioned product was used by Plaintiff, Defendant impliedly warranted to Plaintiff and Plaintiff's agents and physicians that said product was of merchantable quality and safe and fit for the use for which it was intended.

43. Plaintiff was and is unskilled in the research, design and manufacture of the aforementioned product and reasonably relied entirely on the skill, judgment and implied warranty of the Defendant in using the aforementioned product.

44. The aforementioned product was neither safe for its intended use nor of merchantable quality, as warranted by Defendant, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

45. As a result of the aforementioned breach of implied warranties by the Defendant, Plaintiff suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION
(Breach of Express Warranty)

46. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

47. At all times herein mentioned, Defendant expressly warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendant or its authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned product was safe, effective, fit and proper for its intended use.

48. In utilizing the aforementioned product, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of the Defendant. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the uses for which it was intended.

49. As a result of the foregoing breach of express warranties by the Defendant, Plaintiff suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION
(Deceit by Concealment)

50. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

51. Defendant from the time that the aforementioned product was first manufactured, marketed and distributed, and up to the present, willfully deceived Plaintiff by concealing from the Plaintiff, Plaintiff's physicians and the general public, the true facts concerning said pharmaceutical product, which the Defendant, as manufacturers, marketers, and distributors of the product, had a duty to disclose.

52. At all times herein mentioned, Defendant conducted a sales and marketing campaign to promote the sale of the aforementioned drug product and willfully deceived

Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the aforementioned product. Defendant was aware of the foregoing, and that the aforementioned product was not same, fit and effective for human consumption, the use of said product is hazardous to health, and said product has serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff as delineated herein.

53. The Defendant intentionally concealed and suppressed the true facts concerning said pharmaceutical product with the intent to defraud Plaintiff, in that the Defendant knew that Plaintiff's physicians would not prescribe the subject product, and Plaintiff would not have used the subject product, if aware of the true facts concerning the dangers of said product.

54. As a result of the foregoing fraudulent and deceitful conduct by the Defendant, Plaintiff suffered injuries and damages as alleged herein.

SEVENTH CAUSE OF ACTION
(Negligent Misrepresentation)

55. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

56. Defendant from the time that the aforementioned product was first manufactured, marketed and distributed, and up to the present, made false misrepresentations, as previously set forth herein, to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that said pharmaceutical product, alone and in combination, was safe, fit and effective for human consumption. At all times herein mentioned, Defendant conducted a sales and marketing campaign to promote the sale of the aforementioned drug product and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the aforementioned product.

57. The Defendant made the foregoing representations without any reasonable ground

for believing them to be true. These representations were made directly by Defendant, by sales representatives and other authorized agents of said Defendant, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject matter.

58. The foregoing representations by the Defendant were in fact false, in that the aforementioned product was not same, fit and effective for human consumption, the use of said product is hazardous to health, and said product has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff as delineated herein.

59. The foregoing representations by Defendant were made with the intention of inducing reliance and the prescription, purchase and use of the subject product.

60. In reliance on the misrepresentations by the Defendant, Plaintiff was induced to purchase and use the aforementioned product. If Plaintiff had known of the true facts and the facts concealed by the Defendant, Plaintiff would not have used the subject product. The reliance of Plaintiff upon Defendant's misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities who were in a position to know the true facts.

61. As a result of the foregoing negligent misrepresentations by the Defendant, Plaintiff suffered injuries and damages as alleged herein.

EIGHTH CAUSE OF ACTION
(Violation of Consumer Protection Statutes)

62. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

63. Consumer fraud statutes in South Dakota and in other states prohibit the act, use, or employment of any fraud, false pretense, false promise, misrepresentation, misleading

statement or deceptive practice in connection with the sale of any merchandise. Consumer fraud statutes in South Dakota and in other states also prohibit conduct which creates a likelihood of confusion or of misunderstanding.

64. Defendant has engaged in acts and practices, as described in this complaint, which were and are likely to mislead the general public in violation of these consumer protection statutes. Defendant has advertised, marketed and sold this drug through the use of misleading, incomplete and deceptive advertising, promotion and product identification, in violation of the consumer protection statutes of this and all other states.

65. At all times herein mentioned Defendant has violated the consumer fraud laws and the false advertising act by disseminating untrue and misleading statements and engaging in conduct likely to deceive consumers, by engaging in acts and practices with intent to induce members of the public to purchase and use Baycol.

66. This conduct includes, but is not limited to, representing to Plaintiff, Plaintiff's physicians and the general public that said pharmaceutical product is safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the Plaintiff, Plaintiff's physicians and the general public that said product had a serious propensity to cause injuries to users, and purposely downplaying and understating the health hazards and risks associated with this drug.

67. The foregoing practices constitute false and misleading advertising, unlawful trade practices, and deceptive trade practices within the meaning of the consumer protection statutes in South Dakota and other states.

68. The unlawful, unfair and fraudulent business practices of Defendant described above present a continuing threat to members of the public in that Defendant continues to engage

in the conduct described therein.

69. As a result of its conduct described above Defendant has been and will be unjustly enriched. Specifically, Defendant has been unjustly enriched by receipt of millions of dollars from the sale and prescription of said drugs, sold in large part as a result of the acts and omissions described herein.

70. Because of the fraudulent misrepresentations made by Defendant as detailed above, and the inherently unfair practice of committing a fraud against the public by misrepresenting and concealing material information, the acts of Defendant described herein constitute unfair or fraudulent business practices.

71. Plaintiff seeks an order of this Court compelling the Defendant to provide restitution, and to disgorge the monies collected and profits realized by Defendant as a result of its unfair business practices, and injunctive relief calling for Defendant to cease such unfair business practices in the future.

72. Plaintiff also seeks injunctive relief in the form of a court-administered medical monitoring program, to be funded by Defendant, to provide Plaintiff and the class members with medical monitoring as supported by the evidence. Said program would be funded through disgorgement of monies collected by Defendant.

NINTH CAUSE OF ACTION
(Medical Monitoring)

73. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

74. As a proximate result of his exposure to Baycol, Plaintiff and the class members have a significantly increased risk of serious latent disease, including potentially fatal muscle cell damage and kidney damage. Plaintiff has been harmed in that he is in immediate need of

medical monitoring.

75. Plaintiff and the class members are entitled to recover the cost of ongoing periodic medical monitoring, reasonably needed to monitor their condition. Class members are entitled to recover this expense, even if the initial medical monitoring does not demonstrate a present physical injury sufficient to sustain a personal injury action under traditional tort law, as the monitoring would not be necessary but for the Defendant's legally wrongful conduct which exposed Plaintiff and the class members to the unreasonably dangerous and defective drug.

76. Early detection of these injuries would allow Plaintiff and the class members to seek medical treatment and to take other actions to protect their health. Failure to detect these diseases and begin treatment early in their progression may make successful treatment more difficult and may increase the risk that Plaintiff and the class members may suffer more serious injuries - including premature death - that could have been minimized or avoided altogether by early detection and treatment. Early detection of these latent diseases through medical monitoring promotes public health and safety in that treatment can alter the course of that disease and detection can prevent other harmful consequences.

77. Health care assessments specially focusing on the risks associated with this drug are different from the standard medical regime recommended in the absence of exposure to Baycol. Such medical monitoring is reasonably necessary according to contemporary scientific principles.

78. A court ordered and supervised medical monitoring program for Plaintiff is an appropriate and necessary form of injunctive relief. Alternatively, a damage award equal to the cost of reasonably necessary medical monitoring can be included as an element of damages.

CLASS ACTION ALLEGATIONS

79. The proposed class is so numerous that joinder of all members is impracticable. Defendant has manufactured, distributed and/or sold millions of units of the drug Baycol which have caused, or are likely to cause, the damages described herein. Approximately 700,000 Americans have used Baycol since its introduction.

80. The questions of law and fact arising out of claims made by the proposed class are common to the class and include, but are not limited to, establishing facts to resolve the following questions of law:

a. Whether the drug Baycol designed, developed, manufactured, distributed, advertised, promoted and/or sold by defendant contains a defect;

b. Whether the drug Baycol manufactured, distributed and/or sold by Defendant cause or contribute to the adverse medical conditions suffered by the class including, without limitation: muscle cell damage; kidney damage; and other adverse medical conditions;

c. When the defendant knew or should have known that the aforementioned medical problems were associated with the drug Baycol and were causing damage to users of the drug Baycol;

d. When the defendant conducted the testing, if at all, of the drug Baycol, the manner in which the testing was conducted, and the results thereof;

e. Whether the testing was adequate and responsible;

f. Whether defendant accurately reported on the testing of the drug Baycol;

g. Whether the drug Baycol is unreasonably dangerous;

h. Whether the defendant was negligent in selling the drug Baycol without adequate testing or warnings;

i. Whether the defendant was negligent in failing to warn of

its lack of knowledge of the effects of the drug Baycol on the human body;

j. Whether the warnings, if any, that were given by defendant were reasonable in light of what they knew or should have known;

k. Whether defendant's failure to give adequate and timely warning of the dangers of the drug Baycol constitutes negligence per se;

l. Whether defendant breached implied warranties in conjunction with the manufacture, marketing, sale and distribution of the drug Baycol;

m. Whether defendant breached express warranties in conjunction with the manufacture, marketing, sale and distribution of the drug Baycol;

n. Whether defendant concealed adverse information from Plaintiff and the class regarding the testing and safety of the drug Baycol;

o. Whether the defendant continued to sell the drug Baycol after it knew or should have known of the defects and of the injuries and risk associated with its use;

p. Whether the defendant is strictly liable to those injured by the drug Baycol;

q. Whether the Plaintiff and members of the class sustained injuries and damages;

r. Whether defendant manufacturer is liable to the class for compensatory damages;

s. If Plaintiff and the class members have sustained injuries and damages, what is the proper mechanism for assessing and awarding damages and administering other relief;

t. Whether use of this drug significantly increases the risk of serious latent disease;

u. Whether medical monitoring is appropriate to promote the early detection of latent conditions, diseases or health hazards made more likely by the use of Baycol; and

v. If medical monitoring is appropriate, the scope and extent of the monitoring reasonably necessary to protect Plaintiff and the class.

81. The claims of the proposed class representative are typical of the claims of the proposed class. More particularly, Plaintiff has sustained injuries and damages from the use of the drug Baycol which are typical of the injuries and damages sustained by the class.

82. Plaintiff will fairly and adequately represent and protect the interests of all members of the described class. Plaintiff has retained attorneys experienced in the prosecution of class actions, including complex product litigation, and mass accident class actions, to represent class members herein.

83. The common questions of law and fact as shown above predominate over individual questions of causation of individual damages and the monetary compensation therefore and defenses of individual defendants are generally applicable to the entire class rather than to individual claims.

84. Concentrating this litigation in one forum will aid with judicial economy and efficiency and promote parity among the claims of individual class members as well as judicial consistency.

85. A class action is superior to other available methods for the fair and efficient adjudication of this litigation, since individual joinder of all members of each class is impracticable. Even if any class members could afford individual litigation, it would be unduly burdensome to the Courts in which the individual litigation would proceed. Individual litigation magnifies the delay and expense to all parties in the court system of resolving the controversies engendered by defendant's product. By contrast, the class action device present far and fewer management difficulties and provides the benefits of unitary adjudication, economies of scale,

and comprehensive supervision by a single court. Thousands of individual actions will create unnecessary burdens on and delay to injured victims in addition to straining the judicial system. Such individual actions will also magnify the expense for retaining expert witnesses, prolong an individual's ability to receive adequate medical care and medical monitoring for the injuries caused by the drug Baycol, and prolong the emotional stress for past users of the drug Baycol.

86. Furthermore, class certification is appropriate because the prosecution of separate actions by individual members of the class would create a risk of adjudications with respect to individual members of the class which would as practical matter be dispositive of the interests of the other members not parties to the adjudications and substantially impair their ability to protect their interests.

87. Accordingly, class certification is appropriate under the Federal Rules of Civil Procedure, Rule 23(b)(2) and/or Rule 23(b)(3) and the class action vehicle is the superior method for handling this litigation.

WHEREFORE, Plaintiff requests judgment against Defendant as follows:

1. For an order certifying the class and any appropriate subclasses thereof under the appropriate provisions of Federal Rules of Civil Procedure, Rule 23, and appointing Plaintiff and his counsel to represent the Class;

2. After due proceedings are had, including trial by jury, that judgment be rendered in favor of Plaintiff and the class and against defendant in an amount to compensate the Plaintiff and each member of the class for all damages including exemplary damages if applicable to which they are entitled by law;

3. For an award of equitable relief commonly denominated medical monitoring, including but not limited to research, medical evaluation and treatment, and all such other functions necessary to ensure the safety of all class members who consumed the drug Baycol;

4. For legal interest on all damages awarded from date of judicial demand until paid;

5. For attorneys fees as allowed by law;

6. For the costs of this litigation; and

7. For such other and further damages and relief as this Court may deem just and proper.

TRIAL BY JURY IS HEREBY DEMANDED.

Respectfully submitted this 15th day of October, 2001.

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